

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

BRIAN EVANS,

Plaintiff,

v.

GILEAD SCIENCES, INC., *et al.*,

Defendants.

Case No. 20-cv-00123-DKW-KJM

**ORDER DIRECTING SERVICE OF
THE FIRST AMENDED
COMPLAINT.¹**

On March 27, 2020, the Court entered an Order dismissing *pro se* Plaintiff Brian Evans' Complaint with leave to amend. Dkt. No. 7. On April 1, 2020, Evans, still proceeding *pro se*, filed a First Amended Complaint (FAC), Dkt. No. 8, against Gilead Sciences, Inc., and the Doe Defendants for damage to his joints as a result of ingesting Truvada, a prescription medication manufactured by Gilead. *Id.* at 9. Liberally construing the FAC, and setting aside "missing or inaccurate legal terminology," *Blaisdell v. Frappiea*, 729 F.3d 1237, 1241 (9th Cir. 2013), Evans asserts the following product liability claims under theories of strict liability and negligence: (1) failure to warn; (2) negligence; (3) design defect; (4) fraud; and (5) breach of express and implied warranty.

¹Pursuant to Local Rule 7.1(c), the Court finds these matters suitable for disposition without a hearing.

Because Evans has alleged sufficient facts to support his claims, this action may proceed with service of Defendant Gilead.²

I. FACTUAL BACKGROUND

In the FAC, Evans asserts that Defendant Gilead Sciences, Inc. (Gilead) manufactured and marketed the prescription medication Truvada. *See* Dkt. No. 8 at 4, 8.³ Evans claims his healthcare provider prescribed him Truvada without any testing or blood work. *Id.* at 2, 7. As it pertains to Gilead, Evans alleges that Truvada contains tenofovir disoproxil fumarate (TDF), which was approved by the Food and Drug Administration (FDA) in October 2001. *Id.* at 4. As early as 1997, studies had shown that the toxicity of TDF is associated with bone and kidney damage, *see id.* at 7–8, and according to one study, patients who had taken Truvada demonstrated accelerated losses of bone density, resulting in osteoporosis and other joint and bone conditions. *Id.* at 2–3. In 2001, Gilead knew that Truvada had to be taken by consumers in high doses to be effective, and thus, patients taking Truvada are at a higher risk for bone and kidney damage. *Id.* at 2, 4, 7.

²The Court subjects each civil action commenced pursuant to 28 U.S.C. § 1915(a) to screening and can order the dismissal of any claims it finds “frivolous or malicious”; “fails to state a claim on which relief may be granted”; or “seeks monetary relief against a defendant who is immune from such relief.” *See* 28 U.S.C. § 1915(e)(2)(B).

³Truvada is a “pre-exposure prophylaxis” (PrEP) medication “that can help reduce the risk of getting HIV-1 through sex, when taken every day and used together with safer sex practices.” Gilead Sciences, Inc., Truvada, <https://www.truvada.com/> (last visited April 3, 2020).

Evans alleges Gilead intentionally omitted an adequate warning of these risks on its prescriber and patient labeling for Truvada. *Id.* at 7. Evans also asserts that Gilead failed to warn doctors of the need to monitor TDF patients for adverse effects. *Id.* at 7–8. In 2002, Gilead allegedly went so far as to make statements that Truvada did not cause kidney failure. *Id.* at 2. Gilead’s sales reps and CEO claimed TDF was a “miracle drug,” had “no toxicities,” and was “benign” and “extremely safe.” *Id.* at 8. In 2002, the FDA allegedly issued Gilead a notice for making deceptive comments about Truvada to consumers. *Id.* at 3. The following year, the FDA issued another warning to Gilead for the same reasons, but Gilead allegedly failed to comply. *Id.* Gilead received a third warning from the FDA, ordering the company to remove a sponsored link for Truvada that failed to mention the potential risks of bone and kidney damage. *Id.* at 2–3.

In April 2001, scientists published research for a different chemical known as tenofovir alafenamide fumarate (TAF). *Id.* at 4. TAF was allegedly shown to be substantially more effective against HIV, resulting in potentially far less toxicity. *Id.* at 5. Evans alleges Gilead began clinical trials for TAF but kept the results secret and eventually announced in 2004 that it was abandoning research for TAF. *Id.* According to Evans, Gilead “purposefully withheld” TAF, knowing that it was “safer,” so that the company could “make more money” by continuing to sell

Truvada until the Truvada patents expired and the medication could be purchased from generic prescription drug manufacturers. *See id.* at 5, 7; *id.* at 2. In 2010, Gilead began publishing the results of its earlier studies on TAF, and in November 2015, the FDA approved TAF. *Id.* at 5. Sometime in 2018, multiple lawsuits were filed against Gilead for the adverse effects of Truvada and the inadequate warnings allegedly provided by Gilead. *Id.* at 3, 6.

As a result of ingesting Truvada and Gilead’s alleged acts and omissions, Evans alleges that he has developed irreversible diffuse arthralgia (joint pain) and is unable to work. *Id.* at 2, 6–7. To further support his allegations, Evans attaches a letter from his treating physician, stating in part, that Evans did not have “multi-joint pain prior to taking the medication.” Dkt. No. 8-1.

II. SCREENING

“The standard for determining whether a plaintiff has failed to state a claim upon which relief can be granted under § 1915(e)(2)(B)(ii) is the same as the Federal Rule of Civil Procedure 12(b)(6) standard for failure to state a claim.” *Watison v. Carter*, 668 F.3d 1108, 1112 (9th Cir. 2012). In making this determination, “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Having reviewed the FAC, the Court's March 27, 2020 Order, as well as relevant statutes and case law, the Court finds that the claims in this action may proceed such that Gilead may be served. This, of course, does not mean that the Court deems Evans' claims to be valid, only that they may proceed. Gilead, or any other Defendant joined later in this action, may still challenge Evans' claims through any means procedurally permitted by the Federal Rules.

III. Service

Because Evans has been granted leave to proceed *in forma pauperis*, and because his claims as identified above may proceed, the Court finds that service of the Summons and FAC is appropriate. To facilitate service, the Court ORDERS as follows:

1. The Clerk's Office is directed to send to Plaintiff: one copy of the First Amended Complaint, Dkt. No. 8; one summons; one USM-285 form; one Notice of Lawsuit and Request for Waiver of Service of Summons form (AO 398); two (2) Waiver of Service of Summons forms (AO 399); an instruction sheet; and a copy of this Order. The Clerk shall also send a copy of this Order to the U.S. Marshal. Plaintiff shall complete the forms as directed and submit the following documents to the U.S. Marshal in Honolulu, Hawaii: a completed

USM-285 form; a copy of the First Amended Complaint; the summons; a completed Notice of Lawsuit and Request for Waiver of Service of Summons form (AO 398); and two (2) completed Waiver of Service of Summons forms (AO 399).

2. Upon receipt of these documents from Plaintiff, the U.S. Marshal shall mail to Gilead Sciences, Inc.: a copy of the First Amended Complaint; a completed Notice of Lawsuit and Request for Waiver of Service form (AO 398); and two (2) completed Waiver of Service of Summons forms (AO 399), as directed by Plaintiff without payment of costs. *See Fed.R.Civ.P. 4(c)(3).*
3. The U.S. Marshal shall retain the summons and a copy of the First Amended Complaint. The U.S. Marshal shall file a returned Waiver of Service of Summons form as well as any Waiver of Service of Summons form that is returned as undeliverable, as soon as it is received.
4. If Gilead does not return a Waiver of Service of Summons form within sixty days from the date that such forms are mailed, the U.S. Marshal shall:

- a. Personally serve Gilead pursuant to Rule 4 of the Federal Rules of Civil Procedure and 28 U.S.C. § 566(c).
 - b. Within ten days after personal service is effected, file the return of service for Gilead, along with evidence of any attempts to secure a waiver of service of summons and of the costs subsequently incurred in effecting service on Gilead. Said costs shall be enumerated on the USM-285 form and shall include the costs incurred by the U.S. Marshal's office in photocopying additional copies of the summons and the First Amended Complaint and for preparing new USM-285 forms, if required. Costs of service will be taxed against the personally served Defendant in accordance with the provisions of Federal Rule of Civil Procedure 4(d)(2).
5. Evans is cautioned that if he fails to comply with this Order and his non-compliance prevents timely and proper service as set forth in Federal Rule of Civil Procedure 4(m), this action is subject to dismissal for failure to serve. In addition, should he wish to serve the Summons and First Amended Complaint without the assistance of the U.S. Marshal, Evans may do so pursuant to Fed.R.Civ.P. 4.

6. After service of the First Amended Complaint, Evans must serve on Gilead or its attorneys a copy of all further documents submitted to the Court. The U.S. Marshal is not responsible for serving these documents on Plaintiff's behalf. Evans shall include, with any original paper filed with the Clerk of Court, a certificate stating the date that an exact copy of the document was served on Evans or its counsel, and the manner in which service was accomplished. Any paper received by a District or Magistrate Judge that has not been filed with the Clerk of Court or that does not include a certificate of service will be disregarded.
7. Until the First Amended Complaint is served and Gilead or its attorney(s) file a notice of appearance, Evans should not file motions or other documents with the Court. Evans is further notified that he must comply with the Federal Rules of Civil Procedure and the Local Rules for the District of Hawaii.


CONCLUSION

This case may proceed with service of Defendant Gilead Sciences, Inc. Service shall take place in accordance with the terms of this Order.

IT IS SO ORDERED.

Dated: April 7, 2020 at Honolulu, Hawai‘i.




Derrick K. Watson
United States District Judge

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